I. Claims 43, 46, 49, 50, 53, drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:4, classified in class 530, subclass 399, for example.

II. Claims 44, 47, 49, 51, 54, drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:8, classified in class 530, subclass 399, for example.

III. Claims 45, 48, 49, 52, 55, drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:10, classified in class 530, subclass 399, for example.

IV. Claim 56, drawn to an antibody to a polypeptide comprising the amino acid sequence of SEQ ID NO:4 classified in class 530, subclass 387., for example.

V. Claim 57, drawn to an antibody to a polypeptide comprising the amino acid sequence of SEQ ID NO:8, classified in class 530, subclass 387.1, for example.

VI. Claim 58, drawn to an antibody to a polypeptide comprising the amino acid sequence of SEQ ID NO:10, classified in class 530, subclass 387.1, for example.

VII. Claim 59-60, drawn to a nucleic acid which hybridizes to SEQ ID NO:3 and encodes a VEGF-B molecule, classified in class 536, subclass 23.5, for example.

VIII. Claims 61, 65, drawn to a nucleic acid molecule which encodes an amino acid sequence of SEQ ID NO:4, classified in class 536, subclass 23.5, for example.

IX. Claims 62, 66, drawn to a nucleic acid molecule which encodes an amino acid sequence of SEQ ID NO:6, classified in class 536, subclass 23.5, for example.

X. Claims 63, 67 drawn to a nucleic acid molecule which encodes an amino acid sequence of SEQ ID NO:8, classified in class 536, subclass 23.5, for example.

XI. Claims 64, 68, drawn to a nucleic acid molecule which encodes an amino acid sequence of SEQ ID NO:10, classified in class 536, subclass 23.5, for example.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents eleven separate and distinct inventions. The Examiner admits that Groups "(I-III) and (IV-VII) are related as product and process of use". The Examiner alleges that the "polypeptides of Groups I-III could be used in an entirely different method". The Examiner also admits that Groups "(I-III) and (VIII-XI) are related as product and process of use". The Examiner alleges, however, that "the nucleic acids of

Groups VIII-XI could be used for an entirely different purpose". The Examiner also alleges that Groups I-XI are unrelated based on the "specific structure of each compound" and that "the claims of Groups I-IX lack a common utility...". As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect to prosecute with traverse, the subject matter of Group VII, Claims 59-60, drawn to a nucleic acid molecule which hybridizes to SEQ ID NO:3 and encodes a VEGF-B molecule.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent <u>and</u> distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. The Examiner has specifically justified the restriction requirement in this case by reference to the different subclasses of the Patent and Trademark Office classification system in which the eleven groups of claims would allegedly be classed. This basis fails to justify the restriction requirement in this application. Notably, the alleged separate inventions I to III, IV to VI and VII to XI have the

same classification. Prima facie then there would be no necessity for non-coextensive literature searches in relation to this molecule. The defined molecules are all splice forms of VEGF-B and a literature search for one of these molecules could be expected the retrieve the others.

Moreover, reliance on the classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the subclass(es) with which the Examiner associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Accordingly, Groups I-XI are very clearly interrelated and interdependent, not "independent and distinct".

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicants financial resources, a practice which arbitrarily imposes eleven-way restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the implementation of the General Agreement on Trade and Tariffs (GATT), Applicants are required either to conduct simultaneous prosecution, as here requiring excessive filing costs, or otherwise compromise the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal

challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicants legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

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